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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,595	08/06/2001	Irena Slage	A7949	9500

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EXAMINER

SALAD, ABDULLAHI ELMI

ART UNIT PAPER NUMBER

2157

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,595	SLAGE ET AL.	
	Examiner	Art Unit	
	Salad E. Abdullahi	2157	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-27 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-27 and 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

1. The amendment filed on 5/4/2005 has been received and made of record.
2. Applicant's argument with respect claims 1, 2, 4-27 and 35-39 have been fully considered but are moot in view of new grounds of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown U.S. Patent No. 6,381,577[hereinafter Brown].

As per claim 1, Brown discloses data management method, comprising:

Providing a data engine(server 18)(see fig. 1);

obtaining first observation automatically recorded by a data sampling device

(monitoring device 28) (measuring glucose or blood pressure) (see col. 6, lines 26-41);

and a second observation manually recorded by a user (responses to the queries by the user) (see col. 6, line 66 to col. 7, line 7), said first and said second observation defining

plurality of different observations, said plurality of different observation relating to data of an identical subject (physiological condition of a patient) (see col. 6, line 26-35);

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sending said plurality of different observations to said data engine (see col. 6, lines 26-31);

storing said plurality of different observations database under control of said data engine (see fig. 2 and col. 6, lines 42-50); and

in response to a report request:

retrieving said plurality different observations from said database in accordance with parameters in said report request provide plurality of a retrieved observations (see col. 10, lines 62 to col. 11, line 4); and

producing a report based on said plurality of retrieved observations(see col. 10, lines 62 to col. 11, line 4).

As per claim 39, the data management method as set forth in claim 1, further comprising obtaining from a remote database source a third observation relating to said subject the remote data source being a remote database (see fig. 2 and col. 6, lines 42-50);

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 2, 14-15 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harren et al., U.S. Patent No. 6,108,635 in view of Brown.

As per claim 2, and 14-15, Harren discloses clinical trial data management server method comprising:

receiving, at server(Integrated Disease Information System 10), a user profile (patient information) provided by a client(see fig. 2 and col. 10, lines 49-63);

based on said user profile, indicating to said client one or more matching clinical trials col. 10, lines 49-63), receiving a clinical trial selection from said client col. 10, lines 49-63);

providing to said client a selected clinical trial module (clinical trial module 14) indicated by said clinical trial selection and corresponding a selected one of said matching clinical trials (col. 29, lines 20-60).

the modules being adapted to obtain clinical trial data including a respective data observation(see col. 28, lines 60-67 and col. 29, lines 20-60).

Harren is silent regarding:

receiving at said server said respective data observations;

storing said respective data observation in a database of data observations;

and in response to a report request:

retrieving selected ones of said data observations from said database in accordance with parameters in said report request to provide a plurality of retrieved observations and producing a report based on said plurality of retrieved observations.

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Brown in an analogous art discloses a multi-user monitoring system including:
receiving at said server said respective data observations (see fig. 2 and col. 6, lines 42-50);
storing said respective data observation in a database of data observations(see fig. 2 and col. 6, lines 42-50); and
in response to a report request:
retrieving selected ones of said data observations from said database in accordance with parameters in said report request to provide a plurality of retrieved observations (see col. 10, lines 62 to col. 11, line 4);and
producing a report based on said plurality of retrieved observations(see col. 10, lines 62 to col. 11, line 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the teaching of Brown into system of Herren to enable dynamic monitoring and collection of healthcare information of respective patients.

As per claims 26-27, the claim include features similar to those of claim 14-15, thus claims 26-27are rejected same rational as claim 14-15.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4-13, 16-19 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herren as applied to claim 2 and further in view of Linder.

As per claim 4, Herren discloses substantial features of the claimed invention as discussed above with respect to claim

Herren is silent regarding: wherein said clinical trial data is provided to said server by a medical device.

Linder discloses a data management server for receiving medical data provided the said server by medical device (see fig. 1 and col. 3, lines 42-61). Therefore, it would have been obvious to one having ordinary skill in the art at time of the invention to incorporate the teachings of Linder such as wherein said clinical trial data is provided to said server by a medical device such that accurate clinical trial information can be matched and provided to the respected user (see col. 28, lines 60-67 and col. 29, lines 20-60).

As per claim 5, Linder discloses the data management server method as set forth claim 3, wherein said clinical trial data is provided to said server over the Internet (see fig. 2).

As per claim 6-7, Linder discloses the data management server method as set

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forth in claim 3, wherein said clinical trial data is provided to said server by general-purpose computing device having said clinical trial data manually inputted by a user (see fig. 1 and col. 4, lines 14-43).

As per claim 8-9, Herren discloses the clinical trial data management server method as set forth in claim 3 wherein:

said server includes a data engine (see fig.2 and col. 10, lines 49-63)

said data engine comprises a health data management module (10) (see fig.2 and col. 10, lines 49-63);

and a clinical trials management module(see fig.2 and col. 10, lines 49-63);

said health data management module comprises data analysis algorithms used by said data engine to analyze said clinical trial data(see fig.2 and col. 10, lines 49-63) and

said clinical trials management module: selects said one more matching clinical trials, based on said user profile(see fig.2 and col. 10, lines 49-63);

provides an approval of said clinical trial selection(see col. 28, lines 60-67 and col. 29, lines 20-60);

and provides said selected clinical trial module(see col. 28, lines 60-67 and col. 29, lines 20-60).

As per claim 10-13, Linder discloses the data management server method as set forth in claim 8, wherein said health data management module comprises data analysis algorithms and adapted to accept data for one or more cardiology data, diabetes data,

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allergy data, and immunology data (see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20).

As per claim 16, Herren discloses substantial features of the claimed invention as discussed above with respect to claim 15,

Murphy is silent regarding: said data engine is adapted to receive said clinical trial data from a medical device.

Linder discloses a data management server for receiving medical data provided the said server by medical device (see fig. 1 and col. 3, lines 42-61). Therefore, it would have been obvious to one having ordinary skill in the art at time of the invention to incorporate the teachings of Linder such as wherein said clinical trial data is provided to said server by a medical device such that accurate clinical trial information can be matched and provided to the respected user to ensure the health of the user.

As per 17, Linder discloses the clinical trial data server as set forth in claim 16 wherein said data engine adapted clinical trial data over the Internet(see fig. 1).

As per claim 18-19, Linder discloses the clinical data server as set forth in claim 15, wherein said data engine is adapted receive said clinical trial data from a general-purpose computing device(see fig. 1 and col. 4, lines 14-43).

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As per claim 20-25, Linder discloses the clinical trial data server as set forth in claim 15 wherein:

said health data management module comprises data analysis algorithms used by said data engine analyze said clinical trial data(see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20); and

said clinical trials management module:

selects said one based on said user profile(see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20);

provides an approval of said clinical trial selection(see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20);

and provides said selected clinical trial module more matching clinical trials (see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20).

As per claim 35, the claim includes features discussed above with respect to claim 2, further reciting.

providing a plurality of modules adapted to communicate said plurality of different observations to said data engine (see Herren fig. 2 and col. 6, lines 42-50);

as per claim 36, Herren discloses the method of providing a data management server as set forth in claim 35,

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wherein the selected ones of the plurality of modules include a module adapted to handle processing at the server for clients that provide an observation, relating to the given subject, from a remote data source comprising a database (see col. 6, lines 42-50);

9. Claim 37-38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown as applied to claim 1 above, and further in view of Herren.

As per claim 37, Brown discloses substantial features of the claimed invention as discussed above with respect to claim 1,

Brown is silent regarding: providing a plurality of modules adapted to communicate said plurality of different observations to said data engine.

Herren in an analogous art discloses providing a plurality of modules adapted to communicate said plurality of different observations to said data engine (see Herren fig. 2 and col. 6, lines 42-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention presented with teaching of Brown to utilize the plurality of data modules as taught by Herren, because the clinical trials modules assists the user in designing clinical trials based through identification of combinations of patient attributes.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salad E Abdullahi whose telephone number is 571-272-4009. The examiner can normally be reached on 8:30 - 5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ario Etienne can be reached on 571-272-4001. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

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12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Abdullahi Salad
Primary Examiner
8/3/2005